DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 5 1999

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John B. Dubeck, Esq.
Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001

Re: Docket No. 98P-0694/CP1

Dear Mr. Dubeck:

This responds to your citizen petition, dated August 14, 1998, on behalf of Biovail Corporation International and Biovail Laboratories, Inc., requesting that the Food and Drug Administration (FDA) determine the date on which the 180-day exclusivity period begins to run on abbreviated new drug application (ANDA) No. 74-752[1] for diltiazem hydrochloride extended-release capsules (diltiazem).

You specifically request that FDA determine that a first ANDA applicant eligible for 180-day exclusivity has commenced first commercial marketing of its drug under 21 CFR 314.107(c)(1)(i), and thus triggered the exclusivity period, starting no later than the date of ANDA approval in the following instance: the first applicant has entered into a contractual arrangement with the pioneer new drug application (NDA) holder which (1) delays the marketing of the first ANDA drug product beyond the date of final approval of the ANDA, and (2) provides a financial benefit to the pioneer company as a result of the ANDA applicant's agreement to delay introduction of its product into the market (Petition at 1).

Your petition is granted to the limited extent that FDA has determined that the first commercial marketing of diltiazem under ANDA No. 74-752 has commenced, triggering the 180-day exclusivity period.

I. Discussion

The sponsor of ANDA No. 74-752, Andrx Pharmaceuticals, Inc. (Andrx), began commercially marketing its generic version of diltiazem on June 23, 1999. The 180-day exclusivity period to which Andrx is entitled under 21 U.S.C. 355(j)(B)(5)(iv) commenced on that date and will expire on December 20, 1999. Any otherwise eligible ANDA for diltiazem referencing the same listed drug, Cardizem CD,[2] as ANDA No. 74-752 may receive final approval as of December 20, 1999.

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[1] Submitted by Andrx Pharmaceuticals.

[2] Sponsored by Hoechst Marion Roussel, Inc.

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The issues you raised in the petition were considered by the Agency in the recently published proposed rule addressing 180-day exclusivity for generic drugs. (See 64 FR 42873 at 42883-84, August 6, 1999.) The Agency believes that the proposed approach will achieve the goal of prompt marketing of generic products, discussed in your petition and at the heart of the Hatch-Waxman Amendments[3] to the Federal Food, Drug, and Cosmetic Act. If you have further comments related to this issue, the Agency encourages you to submit them to the Dockets Management Branch as described in the proposed rule. (See 64 FR 42873.)

II. Conclusion

Your petition is granted to the limited extent that the 180-day exclusivity period for ANDA No. 74-752 has commenced and generic versions of diltiazem referencing Cardizem CD are eligible for final approval on December 19, 1999.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

[3] The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417).